

REMARKS

The Final Office Action mailed on September 24, 2008 has been reviewed and the comments of the Examiner carefully considered. Claims 1, 3-13, and 19 are pending and currently stand rejected. Claim 1 has been amended. No new matter has been added by way of this amendment.

Rejections under 35 U.S.C. § 103

- 1. Claims 1-2 and 5-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cullen et al. (WO 00/33893).**

The rejections of claims 1-2 and 5-13 made under 35 U.S.C. § 103(a) as being unpatentable over Cullen et al. in the Office Action of February 13, 2008 were maintained in the Final Office Action of September 24, 2008. Regarding independent claim 1, in the Office Action of February 13, 2008, the Examiner alleged that because Cullen et al. states that mixtures of two polysaccharides selected from the group consisting of oxidized celluloses, chitosans, and salts, are suitable for use in compositions which can be used as wound dressings, then one would have a reasonable expectation of success upon combining two things that are each respectively recognized as being suitable in the prior art for a given purpose. Applicants respectfully disagree.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all claim limitations. MPEP § 2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the applicant's disclosure. MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Applicants respectfully submit that Cullen et al. does not teach, suggest, or otherwise disclose:

“A wound dressing composition comprising an intimate mixture of a chitosan and an oxidized cellulose” (emphasis added).

As disclosed in the present specification, the oxidized cellulose is in the form of particles, such as fiber particles or powder particles, preferably dispersed in a suitable solid or semisolid topical medicament vehicle (*see e.g.*, page 3, lines 25-27). The oxidized cellulose is more thoroughly complexed – *i.e.*, an “intimate mixture” – with the chitosan, as discussed below. Cullen et al. merely discloses a sterile composition comprising a complex of a therapeutic peptide and a polysaccharide, and therefore fails to suggest, much less disclose, an “intimate mixture of a chitosan and an oxidized cellulose”.

It is a surprising and unexpected result of the present invention that such intimate mixing results in maximum chemical complexation between the amine groups of the chitosan and the carboxylate groups of the oxidized cellulose (page 5, lines 1-2). In addition, the intimate mixture of oxidized cellulose and chitosan, both having a range of controllable properties, renders them readily available and allows an exceptional degree of control of their properties. In particular, the rate of biological absorption, porosity and density of the materials may be controlled (page 7, lines 9-12). Further, it is a surprising and unexpected result that the intimate mixture of the present invention has an excellent ability to bind to growth factors – in particular, platelet derived growth factor (PDGF) (page 10, lines 10-15).

As Cullen et al. does not disclose an intimate mixture of a chitosan and an oxidized cellulose, the cited reference does not suggest, much less teach, the present invention. Consequently, applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 5-13 (claim 2 having previously been canceled) are thereby allowable as written as depending from an allowable independent claim.

2. Claims 1, 3-4 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Watt et al. (WO 98/00180) in further view of Cullen et al. (WO 00/33893).

The rejections of claims 1, 3-4 and 19 made under 35 U.S.C. § 103(a) as being unpatentable over Watt et al. in further view of Cullen et al. in the Office Action of February 13, 2008 were maintained in the Final Office Action of September 24, 2008. Regarding independent claim 1, in the Office Action of February 13, 2008, the Examiner alleged that although Watt et

VIA ELECTRONIC FILING

al. fails to exemplify a wound dressing comprising both oxidized cellulose and chitosan, Cullen et al. teaches that combinations of polysaccharides can function as wound dressings. Thus, the Examiner stated that one of ordinary skill in the art would expect a reasonable degree of success in combining the teachings of Watt et al. and Cullen et al. because both oxidized cellulose and chitosan have been shown to be functional equivalents. Applicants respectfully disagree.

Watt et al. merely discloses use of oxidized cellulose for the preparation of a medicament for the treatment of a chronic wound. As the Examiner admitted, Watt et al. fails to exemplify a wound dressing comprising both oxidized cellulose and chitosan; thus, Watt et al. fails to suggest, much less disclose, an “intimate mixture of a chitosan and an oxidized cellulose”. Cullen et al. does not cure this deficiency. As noted above, Cullen et al. fails to teach an intimate mixture of a chitosan and an oxidized cellulose. Thus, for the same reasons as stated above, the combination of cited references does not disclose all of the limitations of the applicants’ claim 1.

As neither Watt et al. nor Cullen et al. discloses an intimate mixture comprising a chitosan and an oxidized cellulose, the combination does not suggest, much less teach, the present invention. Consequently, applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 3-4 and 19 are thereby allowable as written as depending from an allowable independent claim.

Rejections under 35 U.S.C. § 112

Claims 1, 3-13, and 19 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Regarding independent claim 1, the Examiner stated that the application fails to provide support for the phrase: “consisting essentially of a chitosan and an oxidized cellulose”. As claim 1 has been currently amended by the deletion of the language “consisting essentially”, these rejections are now moot. Applicants respectfully submit withdrawal of the rejection of claim 1 under 35 U.S.C. § 112. Further, applicants submit that claims 3-13 and 19 are thereby allowable as written as depending from an allowable independent claim.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5337 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5023) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

BREDA M. CULLEN ET AL.

Date: March 23, 2009

By: /Christopher I. Halliday/
Christopher I. Halliday
Registration No. **42,621**

MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5337
Facsimile: (215) 963-5001
E-Mail: challiday@morganlewis.com